

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



(11) Publication number : **0 599 772 A1**

B6

(12)

EUROPEAN PATENT APPLICATION

(21) Application number : **93630089.6**

(51) Int. Cl.⁶ : **A61B 17/04**

(22) Date of filing : **11.11.93**

(30) Priority : **13.11.92 IL 10373792**

(43) Date of publication of application :
01.06.94 Bulletin 94/22

(84) Designated Contracting States :
CH DE FR GB IT LI

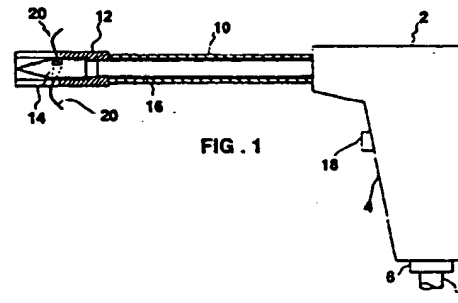
(71) Applicant : **TECHNION RESEARCH AND
DEVELOPMENT FOUNDATION LTD.**
Gutwirth Park,
Technion City
Haifa 32 000 (IL)

(72) Inventor : **Beyar, Mordechai**
7 Haeshkolit Street
IL-30 600 Caesarea (IL)
Inventor : **Foux, Amnon**
68 Horev Street
IL-34 343 Haifa (IL)

(74) Representative : **Schmitz, Jean-Marie et al**
Dennemeyer & Associates Sàrl
P.O. Box 1502
L-1015 Luxembourg (LU)

(54) Stapler device particularly useful in medical suturing.

(57) A stapler device includes a manually grippable handle (4) containing a drive and a trigger to activate the drive mechanism, a barrel (10) fixed to the handle, a guide (12) for holding a staple (14) to be ejected and formed to accommodate a suture thread (20) fixed to the staple, and an ejector (16) driven by the drive through the barrel for ejecting a staple out through the guide into a bone to enable the suture, so anchored to the bone, to be used for various medical operations.



EP 0 599 772 A1

The present invention relates to a stapler device, and particularly to a stapler device useful in medical suturing. The invention is especially useful in treating urinary stress incontinence, and is described below with respect to such an application, but it will be appreciated that the invention could advantageously be used in other applications as well, such as in treating a recurrent shoulder dislocation condition.

Urinary stress incontinence, i.e., the inability to control urination from the bladder, is a distressing problem for more than ten percent of elderly women as well as for many young women. This condition frequently arises in the following manner: In a normally anatomically positioned bladder, the proximal urethra and the bladder are in pressure continuity with the abdominal cavity, so that an increase in abdominal pressure is transmitted both to the bladder and to the proximal urethra, resulting in normal continence. However, particularly among elderly women, the bladder and the proximal urethra tend to descend from their normal anatomic positions such that the bladder neck and proximal urethra move away from the posterior wall of the pubic bone. When this occurs, the proximal urethra is no longer in pressure continuity with the abdominal cavity; therefore, an increase in intra-abdominal pressure (e.g., by laughing or coughing) results in an increase in the intravesical pressure, but no change in the urethral closing pressure, thereby producing stress incontinence. It also appears that as the bladder descends, the urethra becomes shorter and curved, so that its radial tonic muscle contraction is reduced, contributing to incontinence.

Many treatments have been devised to correct stress incontinence. One treatment is by a surgical operation, involving an incision in the abdominal wall and/or interior vaginal wall, to return the bladder and proximal urethra to their normal anatomic positions by elevating them towards the posterior wall of the pubic bone in order to bring them into pressure continuity with the abdominal cavity. Another medical treatment involves a closed operation in which the bladder neck is elevated by suture threads passing, with the aid of long needles, from both sides of the urethra in the bladder neck to the inferior abdominal wall.

An object of the present invention is to provide a stapler device which is particularly useful for fastening threaded staples to a bone for various medical purposes, particularly to treat urinary stress incontinence in the latter type of closed operation.

According to the present invention, there is provided a stapler device comprising: a handle manually grippable by a user containing a drive mechanism and a trigger to activate the drive mechanism; a barrel fixed to the handle; a guide for holding a staple to be ejected; and an ejector driven by the drive mechanism, movable in the barrel for ejecting a staple out

through an end of the guide; characterized in that the end of the guide is formed to accommodate a suture thread fixed to the staple.

Such a stapler device is particularly useful for treating women suffering from urinary stress incontinence caused by the descending of the bladder and the proximal urethra from their normal anatomical positions. Thus, the staple may be ejected through the vaginal wall to enter the pubic bone, and the suture thread secured to the staple may be used for attaching the bladder neck and the proximal urethra to the posterior wall of the pubic bone. Such a stapler device may also be used in other applications, for example in medical operations for the fixation of a shoulder capsule in a person suffering from chronic shoulder dislocation.

The invention also provides a staple including a suture thread secured thereto for ejection by the above-described novel stapler device.

Further features and advantages of the invention will be apparent from the description below.

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

Fig. 1 illustrates one form of stapler device constructed in accordance with the present invention;

Figs. 2 and 3 illustrate the natural curved shape and the temporary straight shape respectively, of one form of staple with attached thread in accordance with the present invention;

Fig. 4 is an enlarged sectional view of the staple guide in the stapler device of Fig. 1;

Fig. 5a is an end view illustrating the staple guide of Fig. 4; Fig. 5b is similar to Fig. 5a, illustrating a modification in the construction of the staple guide;

Figs. 6 and 7 are views similar to Figs. 4 and 5, respectively, illustrating a modification in the construction of the staple guide;

Figs. 8a-8e illustrate various stages in applying the staple and thread of Figs. 2 and 3 to the pubic bone when treating for urinary stress incontinence (or other bone when treating for other conditions).

Figs. 9-11 illustrate modifications in the construction of the stapler device of Fig. 1;

and Figs. 12-18 illustrate other forms of staple-thread units which may be used.

The stapler device illustrated in Fig. 1 comprises a housing, generally designated 2, including a handle 4 which is manually grippable by the user. The illustrated stapler device is pneumatically powered and therefore includes a connector 6 at the bottom of the handle 4 for attaching thereto a tube 8 connectible to a source of pressurized air. Housing 2 further includes an elongated barrel 10 having a staple guide 12 at its end for the staple 14 to be ejected. Ejection

of the staple 14 is effected by an ejector pin 16 which is driven into sharp impact against the base of the staple 14 by the air pressure supplied from the pressurized air tube 8. Handle 4 includes a trigger 18 which, when depressed, applies an air pressure pulse to ejector pin 16 to cause it to impact against the base of staple 14 and thereby to eject the staple out through the end of guide 12. Insofar as described, such staple devices are known, and therefore further details of its construction and operation are not set forth.

As distinguished from the known constructions, the staple 14 ejected from the guide 12 at the end of barrel 10 in Fig. 1 has a suture thread 20 secured to the staple and ejected with it. In the above-described application, the staple is driven into the patient's pubic bone, and the thread 20 may then be used for fixing the bladder neck and proximal urethra thereto.

The staple 14 in Fig. 1 is made of elastic material. The staple is preferably shaped into the curved form illustrated at 14' in Fig. 2 while it is in its normal condition, and is deformed into the straight form shown at 14" in Fig. 3 while in a straight condition. It is loaded into the stapler and ejected therefrom while in its straight stressed condition. After it has been so ejected, it returns to its curved form shown at 14' in Fig. 2, thereby better fixing the staple to the bone tissue it penetrated when ejected from the staple guide 12.

As shown in Figs. 2 and 3, the staple 14 is formed with a pointed end 14a to enable it to penetrate the bone, and with a hole 14b approximately midway of its length for receiving the thread 20, similar to the manner in which a thread is received in the eye of a needle.

Figs. 4 and 5 more particularly illustrate the staple guide 12 from which the staple 14, including its attached thread 20, is ejected. As shown, this guide is formed with a pair of slots 22 to accommodate the thread 20. Thus, when the base 14c of staple 14 is impacted by the ejector pin 16, the thread 20 moves through slot 22, thereby permitting the staple guide 12 to snugly fit around the ejected staple 14.

Figs. 6 and 7 illustrate a modification in the construction of the staple guide 12 in order to accommodate the thread 20 secured to the staple 14. In the modification of Figs. 6 and 7, the inner surface of the staple guide 12 is formed with a pair of recesses 22a for receiving the two sides of the thread 20.

The manner of using the illustrated stapler device will now be described particularly with reference to Figs. 8a-8e.

Thus, the staple 14, together with its attached thread 20, is loaded into the staple guide 12 while the staple is in its straight condition as illustrated at 14" in Fig. 3. Depressing trigger 18 causes a high-pressure pulse of air to be applied to ejector pin 16. This pulse causes ejector pin 16 to impact against the end face 14c of the staple 14, thereby driving the sta-

ple into the bone as shown in Figs. 8a and 8b. As soon as the staple penetrates the bone, it starts to return to its normal, curved shape as shown in Figs. 8c and 8d. The staple is thus firmly anchored to the bone with its attached thread 20 extending through the opening formed by the staple through the bone, as shown in Fig. 8e.

Following is one procedure for performing the above-described operation: A 20F urethral catheter is inserted into the bladder, and a balloon is inflated to 20 cc and retracted gently downwardly against the bladder neck. The surgeon inserts two fingers into the vagina, pressing the interior vaginal wall with one finger on each side of the urethra, which is felt because of the inserted catheter. By pressing the fingers upwardly and backwardly, the bladder neck and proximal urethra are pressed against the posterior wall of the pubic bone. At this stage, two staples are ejected longitudinally on each side of the urethra, about 1-2 cm apart. The two threads on each side of the urethra are tied one to the other. They may be tied on the vaginal mucosa, in which case the tension will embed the threads to the sub-mucosa after some time. Alternatively, the threads may be tied under the vaginal mucosa by passing one of the threads on the same side. The threads may be made of a monofilament non-absorbent material, as well as of an absorbent material, dependent on the preference of the physician.

In cases where the urethra itself is very wide, the threads may be used for engaging and elevating the urethra to the posterior pubic bone as in a "sling operation".

The stapler barrel 10 in Fig. 1 is preferably of a flexible plastic tube. Fig. 9 illustrates a variation wherein the stapler barrel is in the form of a closed helical wire 110 enclosed within a thin flexible tube 111, which increases the flexibility of the barrel and thereby facilitates its placement at the proper direction. Fig. 10 illustrates a variation wherein the barrel, therein designated 210, is a stiff or rigid tube.

Fig. 11 illustrates a further variation wherein the stapler, therein designated 302, includes two barrels 310a, 310b in parallel relation to each other to enable two staples with attached threads to be ejected at the same time. In the modification illustrated in Fig. 11, each of the staple guides 321a, 321b receives a staple-thread unit 314a, 314b ejected by an ejector pin 316a, 316b received in the respective barrel, and both ejector pins are driven at the same time by high pressure pulses produced upon depression of the trigger 318.

Figs. 12-18 illustrate other constructions of staple-thread units which may be used.

The unit illustrated in Fig. 12 includes a staple 114 and a thread 120 similar to the construction illustrated in Figs. 2 and 3, except that the hole 114b through which the thread 120 is passed is at the rear

end of the staple, rather than at the middle.

Fig. 13 illustrates a construction wherein the staple 214 is provided with a bore 214b extending at an angle to the longitudinal axis of the staple 214 with the end of the thread 220 received and fixed therein by crimping the staple. Fig. 14 illustrates a construction wherein the bore 314b is in the base 314c of staple 314 and extends along or parallel to the longitudinal axis of the staple 314, the thread 320 being received within the bore 314b and fixed therein by crimping the staple. Fig. 15 illustrates a construction similar to that of Fig. 14, except that part of the base 414c of the staple 414, formed with the axial bore 414b for receiving the thread 420, is cut away so that the impact of the ejector pin against the base of the staple will not impact against the end of the thread.

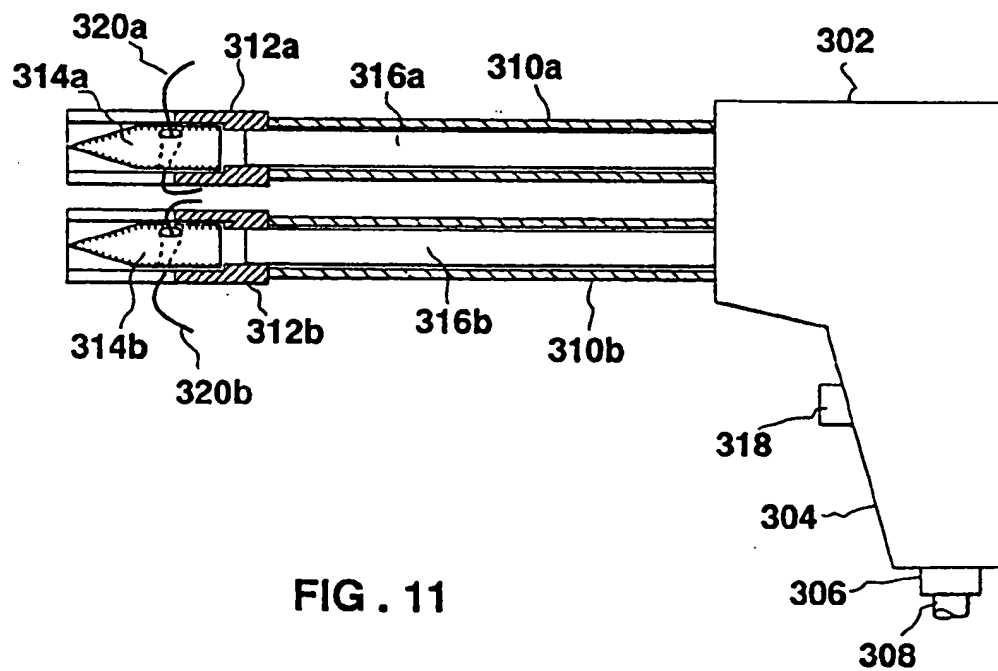
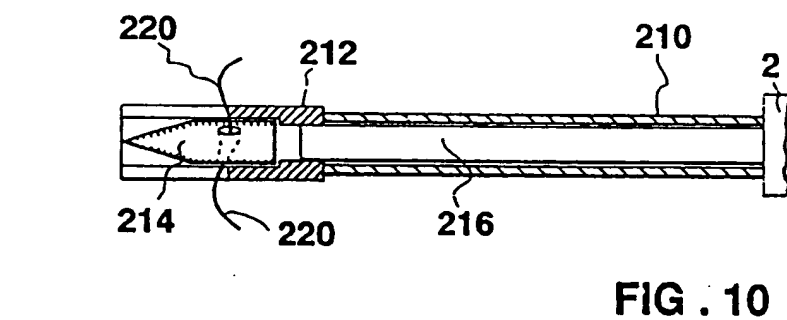
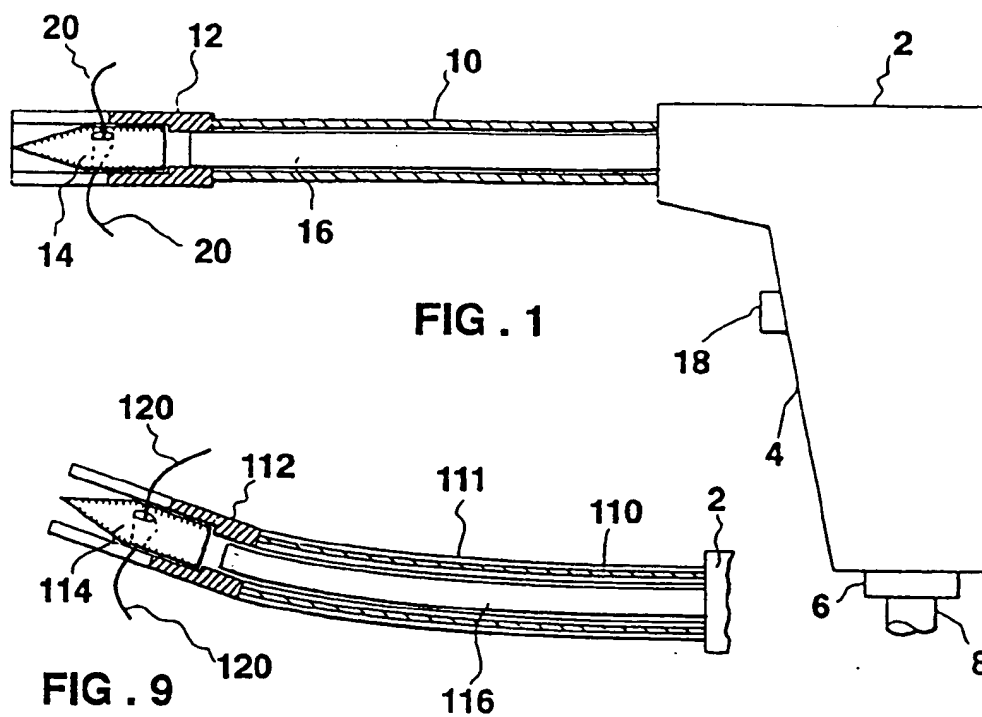
Fig. 16 illustrates a further variation wherein the staple 514 is formed with a plurality of barbs 515 projecting from its outer surface, to fix the staple to the bone which it penetrates. The thread 520 is passed through a hole 514b in the staple.

Fig. 17 illustrates a staple made of bent wire. Fig. 18 illustrates a staple with a split tail 714c, which is straightened when inserted into the staple guide 12.

While the invention has been described with respect to one particular application, it will be appreciated that the described stapler device and stapler-thread units may be used for other applications, e.g., for shoulder dislocations, endoscopic operations, or the like. The stapler may also be electrically operated and may use other mechanical impact devices for driving the stapler. The staples themselves may be of known bio-absorbable materials.

Claims

1. A stapler device, comprising: a handle manually grippable by a user containing a drive mechanism and a trigger to activate the drive mechanism; a barrel fixed to the handle; a guide for holding a staple to be ejected; and an ejector driven by the drive mechanism, movable in said barrel for ejecting a staple out through an end of the guide; characterized in that said end of the guide is formed to accommodate a suture thread fixed to the staple.
2. The stapler device according to Claim 1, wherein said drive is a pneumatic drive, and said handle includes a connector for connecting thereto an air tube supplying pressurized air to the device.
3. The stapler device according to either of Claims 1 or 2, wherein said end of the guide is formed with a recess on its inner surface for receiving the suture thread fixed to the staple.
4. The stapler device according to Claim 3, wherein the internal surface of said end of the guide is formed with two recesses on opposite sides thereof each dimensioned to receive a section of the suture thread fixed to the staple and ejected therewith.
5. The stapler device according to any one of Claims 1-4, wherein the device includes two barrels and two guides in parallel relation to each other and fixed to a common handle, each of said barrels including an ejector for ejecting a staple from its respective guide, said handle including a drive for driving both said ejectors.
6. The stapler device according to any one of Claims 1-4, further including a staple disposed within said guide and having a suture thread secured thereto.
7. A device including a staple and a thread secured thereto.
8. The device according to either of Claims 6 or 7, wherein the staple is formed with a throughgoing hole, and said suture thread is secured to the staple by being passed through said hole.
9. The device according to any one of Claims 6-8, wherein said staple is made of a flexible material and is formed with a curved shape, is temporarily deformed into a straight shape at the time it is ejected, and returns to its curved shape after ejection.
10. The device according to any one of Claims 6-8, wherein the staple is formed with a plurality of barbs projecting from its outer surface.



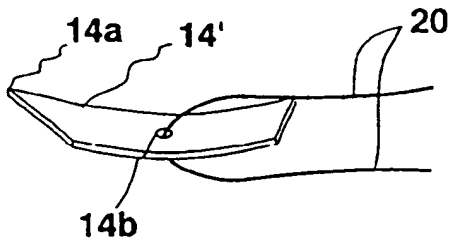


FIG. 2

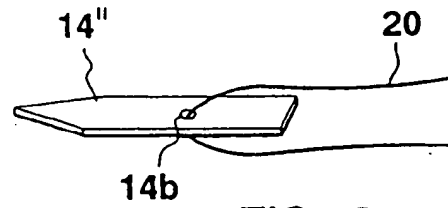


FIG. 3

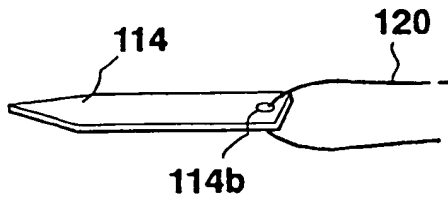


FIG. 12

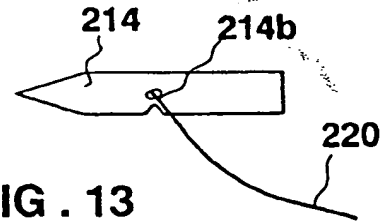


FIG. 13

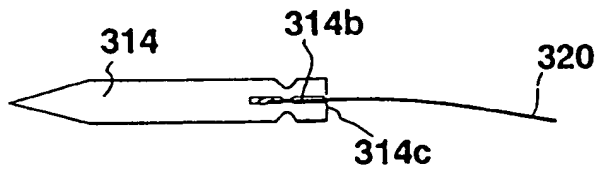


FIG. 14

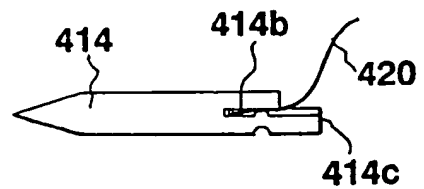


FIG. 15

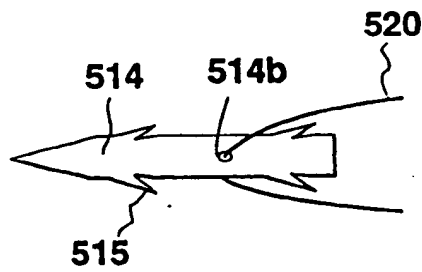


FIG. 16

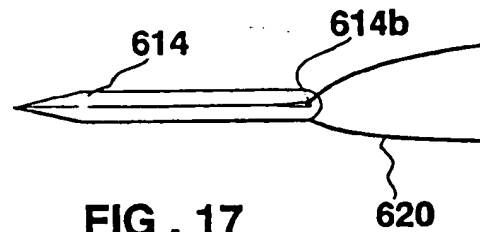


FIG. 17

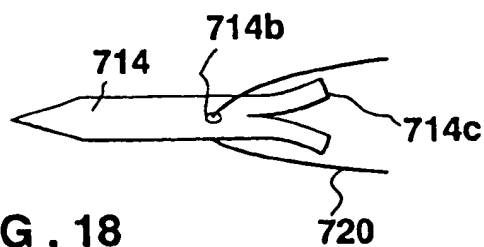


FIG. 18

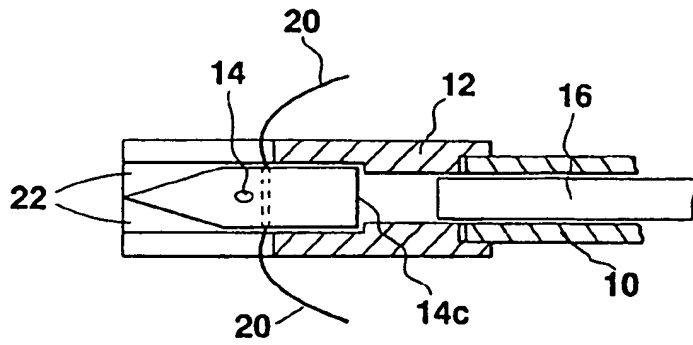


FIG. 4

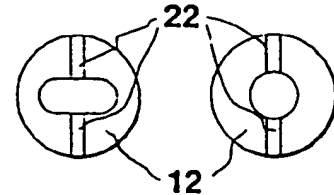


FIG. 5a

FIG. 5b

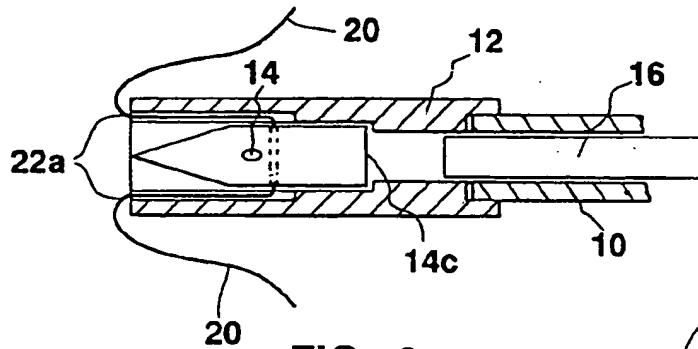


FIG. 6

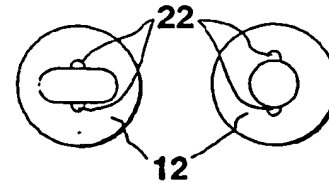


FIG. 7a.

FIG. 7b

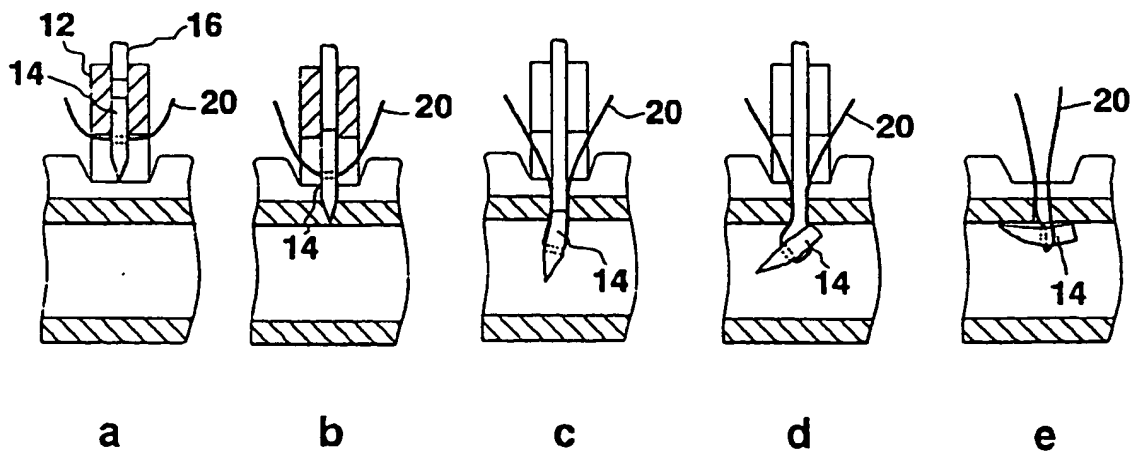


FIG. 8



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 93 63 0089

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cls)
X	FR-A-1 539 593 (A. A. JOHNSON)	1,3-8	A61B17/04
Y	* page 3, right column; figures 3,5,9,10,20 *	2	
Y	US-A-4 422 567 (T. H. HAYNES) * column 4, line 64 - line 68 *	2	
X	EP-A-0 140 557 (E. L. BLACKWOOD) * claim 1; figures 6,8 *	1,5	
X	WO-A-89 10096 (J. O. HAYHURST) * claim 1; figures 1,15,16 *	1,6-10	
P,X	EP-A-0 558 993 (MITEK SURGICAL PRODUCTS) * claims 1,22; figures 1,4A *	1,3,4,6-9	
			TECHNICAL FIELDS SEARCHED (Int.Cls)
			A61B
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 26 January 1994	Examiner Gerard, B
CATEGORY OF CITED DOCUMENTS		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons A : technological background U : non-written disclosure P : intermediate document & : member of the same patent family, corresponding document	
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category			

EPC FORM 1500 (11.93) (P/ACH)